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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,816	11/07/2005	Robert Schegerin	41052/321928	2669

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

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03/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/555,816	Applicant(s) SCHEGERIN, ROBERT	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-38 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Examiner acknowledges claims 20-38 are pending in this application with claims 1-19 having been cancelled, and claims 20-38 having been newly added.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: oronasal face piece 10.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "4a", "4b", "4c", "4d", and "4b" have all been used to designate "part".
4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the oronasal face piece must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.

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- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

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- (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

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- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

5. The disclosure is objected to because of the following informalities: On page 5, Lines 35-38, Applicant discloses, "This part 4b is, for example, also made of silicone or latex, but is thinner than the part 4b." Applicant's disclosure is confusion because Examiner is unsure how part 4b can be thinner than it's self. Examiner requests Applicant review the complete disclosure for any additional inconsistencies. Appropriate correction is required.

Claim Objections

6. Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

7. Claims 20-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 20, the word "means" is preceded by the word(s) "hygienic projection" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element.

Regarding claims 35-38, Applicant's use of the word "part" without specific explanation beyond function language of the differences between each "part" of the hygienic protection means does not provide Examiner with a clear understanding of what is being claimed without undue experimentation. As it appears the recited claim language is indefinite in nature, Examiner requests Applicant clarify the invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 20-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (5,372,130) in view of Kaufman (3,757,777).

As to Claim 20, Stern discloses a respirator face mask (10) providing physiological protection, comprising: an oronasal face piece (24) which is connectable to a respiratory gas source (18), a semi flexible lip element (26) with an edge designed to position said oronasal face piece (24) on a user's face, and hygienic protection means (16) which are removably positioned (Column 6, Lines 15-17) at least partially inside said mask (10) and including a first part (Exhibit A) which provides hygienic protection and a second part (Exhibit A) which maintains said hygienic protection means in the mask, said second part cooperating with the semi-flexible lip element (26) and the face piece (24).

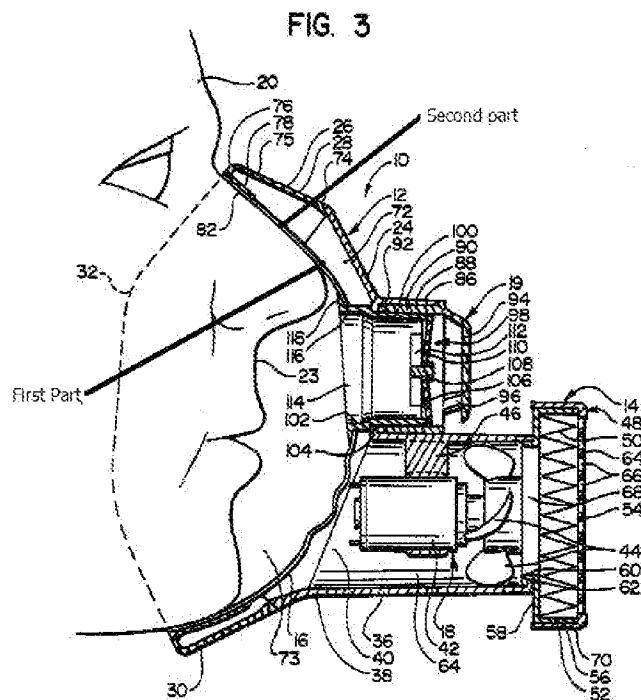


Exhibit A: Examiner modified Figure 3 of Stern (5,372,130)

Yet, Stern does not expressly disclose the cooperation with the second part and the semi-flexible lip to be elastic. However, at the time the invention was made the use of

elastic cooperation with the second part and the semi-flexible lip was known.

Specifically, as the filter device (16) of Stern is capable of being removed from the mask (10) the filter device (16) may be replaced with any other device including but not limited to the device of Kaufman which includes a filter (1) in the first part of the filter and a seal (2) made of a plastic edge on the second part of the filter as Kaufman teaches a dual part filter medium for providing filtering to the first part and a sealing edge on the second part. The combination of these two references would result in the elastic connection of the second part and the sealing edge as both portions are made of plastic. (Figure 1, Column 2, Lines 40-63). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Stern to include a dual part filter medium as taught by Kaufman to provide additional sealing means of the mask to the user.

As to Claim 21, the system of Stern/ Kaufman teaches the first and second filter parts are made of different materials. Specifically, Kaufman teaches the dual part filter system enables the mask to perform both functions of sealing the device to the face of the patient and filtering contaminants.

As to Claim 22, the system of Stern/ Kaufman teaches the second part of said hygienic protection means is in contact with at least an internal part of said semi-flexible lip element. Please see rejection of claim 20.

As to Claims 23 and 24, the system of Stern/ Kaufman teaches a thin lip element of said hygienic protection means prolongs, in at least one area, said second part of said hygienic means, so as to extend a few millimeters beyond said edge of semi-

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flexible lip element. As seen in Figures 6 and 8 of Stern the top portion of the filter (16a and 16b, respectively) extends further up the nose bridge than the oronasal face piece. Kaufman also discloses a second sealing means (4) which extends further beyond the thin lip element (2) for providing sealing means to the filtering mask. Furthermore, Applicant has not asserted the extension of a few millimeters beyond provides any particular advantage, solves a stated problem or serves a purpose different from providing sufficient connection between the users face and the hygienic protection means and the mask, thus the use of the millimeter extension lacks criticality in its design.

As to Claims 25 and 26, Stern discloses the filter (16) filters respiratory gas to protect the user from contamination. (Column 4, Lines 49-63).

As to Claim 27 and 28, Stern discloses the corrugated shape (Figure 3) for reducing the pressure drop of the hygienic protection means. Furthermore, Kaufman teaches the corrugated shape increases the efficiency of the filter. (Column 2, Lines 40-45).

As to Claim 30, the system of Stern/ Kaufman teaches the use of plastic to form the second part of the hygienic protection means and discloses any other material may be used. (Column 3, Lines 1-25). Intrinsically, as silicone is a plastic polymer, silicone is included as a device the second part can be made from. Furthermore, it should be noted that the portion of the recitation that claims the second part is made of silicone is directed to a process. Since the claim is an apparatus/product claim, patentable weight is only given to the end product. "Even though product-by-process claims are limited by

and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is in the same as or obvious form a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As to Claim 31, Stern discloses the hygienic protection means is removable. (Column 2, Lines 15-17). As the device of Stern has a outer filter (14) the device is still operable for use whether the hygienic protection means is present or not and the semi-flexible lip element (26) would be in direct contact with the user’s face.

As to Claims 29, 32-34, and 38, the system of Stern/ Kaufman discloses a flexible structure placed between the hygienic protection means and the internal part of the semi-flexible lip element and extends beyond the semi-flexible lip element. Specifically Kaufman has straps (8) that extend beyond the semi-flexible lip element and around the head of the user to retain the hygienic protection means in place.

As to Claim 35 (as best understood by the Examiner), the system of Stern/ Kaufman discloses a three part filtering mask system. Specifically, Kaufman discloses a first part (1) designed to be pressed onto said user’s face, by the effect of a pressure of respiratory gas inside said mask, when said mask is worn to provide a seal between said hygienic protection means and said user's face, a second part (2) located over an external area of said face semi-flexible lip element which, in absence of said hygienic protection means, would have been in contact with the user’s face once said mask was

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in place on said user's face, and a third part (4) located outside the semi-flexible lip element and including a structural part providing a seal between the semi-flexible lip element and said hygienic protection means.

10. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (5,372,130) in view of Kaufman (3,757,777) as applied to claim 35 above, and further in view of Martin (4,641,379).

As to Claim 36 (as best understood by the Examiner), the system of Stern and Kaufman teaches a respiratory mask with a structural part, yet does not expressly disclose the structural part exerting mechanical pressure on the semi-flexible lip element greater than the maximum pressure of respiratory gas which can prevail inside the mask. However, at the time the invention was made the specifics of the structural part was known. Specifically, Martin teaches a strap (10) for a mask (30) that extends around the circumference of the user's head providing a uniform pressure to the mask thereby allowing a greater degree of comfort to the user. (Figure 3, and Column 3, Lines 55-60). Therefore, it would have been obvious to one having ordinary skill in the art at time the invention was made to modify the system of Stern/Kaufman to include a structural part exerting a mechanical pressure on the user, for increasing the comfort of the wear of the mask by distributing the pressure uniformly.

11. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (5,372,130) in view of Kaufman (3,757,777) as applied to claim 35 above, and further in view of Spector (4,597,781).

As to Claim 37 (as best understood by the Examiner), the system of Stern/Kaufman teaches a three part hygienic protection means with two of the three parts made of plastic, yet does not expressly disclose the third part of the filter is also made of plastic. However, at the time the invention was made the use of plastic in a filter was known. Specifically, Spector teaches the use of plastic filters in the filtration of air (Column 1, Lines 55-58). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Stern/Kaufman to include another portion made with a plastic for the purpose of providing filtering of coarse particles. Furthermore, it should be noted that the portion of the recitation that claims that the three parts are formed of a single elastic film is directed to a process. Since the claim is an apparatus/product claim, patentable weight is only given to the end product. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is in the same as or obvious form a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. White (4,739,755), Woicke (4,361,146), Ward (4,458,679), Bohn et al. (6,860,268), Ennan (GB 2176404), Warncke (GB 2074457).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
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/Annette F Dixon/
Examiner, Art Unit 3771

/Justine R Yu/
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